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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,868

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,868	Applicant(s) ASAKAWA, TOMOKO	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 8-12 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed 10/21/2009. New claims 13-15 have been added. The inclusion of distinct chemical species in the amendment necessitated a Requirement for Restriction.

Applicant's election of species, (a) dipeptidyl peptidase IV inhibitor of the formula of claim 15 in the reply filed on 02/04/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, new claims 13 and 14 have been withdrawn as not being drawn to the elected species.

Applicant's arguments filed 10/21/2009 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

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obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 8-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (WO 2004/024184), EP 1 537 880 provided for translation, in view of Nauck et al. (Diabetes Care, 1998).

Akiyama et al. teach that dipeptidyl peptidase IV, DPP-IV, inhibitors are a useful therapeutic drug for diabetes since they inhibit inactivation of glucagon-like peptide-1, GLP-1, in plasma and potentiate incretin activity [0002]. It has been reported that selective inhibition of DPP-IV activity is important in glucose homeostasis [0006]. The instant invention is capable of appropriately inhibiting DPP-IV activity with superior convenience and compliance [0008]. DPP-IV inhibitory activity can be confirmed by a method utilizing the method of Raymond et al. from Diabetes, vol. 47, pp. 1253-1258. A specific DPP-IV inhibitor can be represented by formula II [0015] and [0027]-[0048]. The formula is substantially the same as the formula of the instant specification which is disclosed as the formula for the compound of instant claim 15.

Akiyama et al. do not teach that the inhibitor of DPP-IV can be used to treat diabetes with sulfonylurea secondary failure.

Nauck et al. teaches that GLP-1 stimulated insulin secretion in mild diabetic patients and in patients who were in poor metabolic control on sulfonylurea treatment, i.e. at the point of sulfonylurea secondary failure (page 1925, 3rd column, 1st paragraph,

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page 1928, Conclusions). A similar glucose threshold for GLP-1 insulin secretion is still active in patients with true sulfonylurea secondary failure, i.e. the mechanism for GLP-1 induced insulin secretion is the same for patients with and without secondary sulfonylurea failure (page 1929, 2nd column, 1st paragraph). Sulfonylureas and related drugs such as rapaglinide, i.e. insulin secretagogue, interact with varying degrees with different types of sulfonylurea receptors; and close ATP-sensitive potassium channels in pancreatic β -cells and thereby stimulate insulin release, i.e. sulfonylurea treatment¹.

Nauck et al. does not teach a DPP-IV inhibitor of the formula of instant claim 15.

Since formula II of Akiyama et al. is substantially the same as that of the instant invention, it would reasonably be expected to represent substantially the same compounds which are taught to exhibit DPP-IV inhibitory activity. Accordingly, at the time of the invention it would have been obvious use any of the inhibitors of DPP-IV of Akiyama et al., including the compound of instant claim 15, to treat diabetes with sulfonylurea secondary failure since the compounds inhibit the inactivation of GLP-1 and would therefore reasonably be expected to stimulate insulin secretion in patients with diabetes with sulfonylurea secondary failure. It would have been obvious to first test to see if a mammal can no longer close an ATP-sensitive potassium channel, in order to determine whether the secondary sulfonylurea failure is due to the potassium channels being opened, resulting in a lack of insulin secretion.

No claims are allowed.

¹ Gribble et al., J. of Diabetes and its Complications, 2003, Abstract and page 11, 1st column, 1st

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612